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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

O'CONNOR et al.

Serial No.: §365(c) of PCT/GB00/00349 Group Art Unit: Unassigned

Filing Date: Even Date Herewith Examiner: Unassigned

Title: HYDROGEL PARTICLE FORMULATIONS

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This Amendment accompanies the §365(c) filing of PCT/GB00/00349. Accompanying this Amendment are marked-up claim and specification pages, showing the amendments made herein.

Entry of these amendments is respectfully requested.

Amendment

In the Specification:

At page 1, before line 1, please insert:

--Cross-Reference to Related Application

This application is a §365(c) filing of International Patent Application No. PCT/GB00/00349, filed February 3, 2000, designating the United States, from which priority is claimed pursuant to 35 U.S.C. §120 and also claims priority under 35 U.S.C. §119(e) from U.S. Provisional Application No. 60/118,334, filed February 3, 1999, which applications are incorporated herein by reference in their entireties--

In the Claims:

Please amend the claims as follows:

3. (Amended) Use according to claim 1, wherein the envelope density of the particles is from 0.8 to 1.5 g/cm^3.

4. (Amended) Use according to claim 1, wherein the pharmacologically active agent is a gene construct.

6. (Amended) Use according to claim 1, wherein the hydrogel is agarose or dextran.

15. (Amended) The method of claim 10, wherein the hydrogel particles in step (b) are contacted with the aqueous composition while in a dry state.

16. (Amended) The method of claim 10, wherein the hydrogel particles in step (b) are contacted with the aqueous composition while in a wet, pre-hydrated state.

17. (Amended) The method of claim 10, wherein the hydrogel particles are selected from the group consisting of agarose, dextran, polyethylene glycol and polybutyleneterephthalate particles.

18. (Amended) The method of claim 10, wherein the active agent is present in the powdered pharmaceutical composition in an amount ranging from about 0.1 to 85 wt% of the composition.

19. (Amended) The method of claim 10, wherein the powdered pharmaceutical composition is formed using a freeze-drying step.

20. (Amended) The method of claim 10, wherein the powdered pharmaceutical composition is formed using a spray-drying step.

23. (Amended) The composition of claim 21, wherein the hydrogel is agarose.

24. (Amended) The composition of claim 21, wherein the active agent is a peptide.

25. (Amended) The composition of claim 21 in combination with written labeling instructions for administration of the particles by transdermal or transmucosal, high-velocity, powder injection.

26. (Amended) A unit dosage form of the composition of claim 21.

27. (Amended) An article of manufacture for the transdermal or transmucosal delivery of a pharmacologically-active agent to a subject, which article comprises a pharmaceutical composition of claim 21 in a container containing a unit dose of active agent.

29. (Amended) The article of manufacture of claim 27, wherein the active agent is a peptide or protein.

30. (Amended) The article of manufacture of claim 27 in combination with written labeling instructions for administration o f the particles by transdermal or transmucosal, high-velocity, powder injection.

31. (Amended) A method for delivering a drug to a subject in need thereof, which method comprises preparing a pharmaceutical composition of claim 24, accelerating said particles to a high velocity, and delivering said accelerated particles into a target skin or mucosal site.

33. (Amended) The method of claim 31, wherein the active agent is a peptide.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached pages are captioned **"Version with markings to show changes made."**

REMARKS

Applicants, by way of this Preliminary Amendment, have eliminated multiple dependencies from the claims. Moreover, the specification has been amended to insert a claim for priority.

Accordingly no new matter has been added by way of the above amendments, and the entry thereof is respectfully requested.

Respectfully submitted,

Date: 8/3/01

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Version with markings to show changes made

The claims have been amended as follows:

3. (Amended) Use according to claim 1 [or 2], wherein the envelope density of the particles is from 0.8 to 1.5 g/cm^3.

4. (Amended) Use according to [any one of the preceding claims] claim 1, wherein the pharmacologically active agent is a gene construct.

6. (Amended) Use according to [any one of the preceding claims] claim 1, wherein the hydrogel is agarose or dextran.

15. (Amended) The method of [any one of claims 10 to 14] claim 10, wherein the hydrogel particles in step (b) are contacted with the aqueous composition while in a dry state.

16. (Amended) The method of [any one of claims 10 to 14] claim 10, wherein the hydrogel particles in step (b) are contacted with the aqueous composition while in a wet, pre-hydrated state.

17. (Amended) The method of [any one of claims 10 to 16] claim 10, wherein the hydrogel particles are selected from the group consisting of agarose, dextran, polyethylene glycol and polybutyleneterephthalate particles.

18. (Amended) he method of [any one of claims 10 to 17] claim 10, wherein the active agent is present in the powdered pharmaceutical composition in an amount ranging from about 0.1 to 85 wt% of the composition.

19. (Amended) The method of [any one of claims 10 to 18] claim 10, wherein the powdered pharmaceutical composition is formed using a freeze-drying step.

20. (Amended) The method of [any one of claims 10 to 18] claim 10, wherein the powdered pharmaceutical composition is formed using a spray-drying step.

23. (Amended) The composition of claim 21 [or 22], wherein the hydrogel is agarose.

24. (Amended) The composition of [any one of claims 21 to 23] claim 21, wherein the active agent is a peptide.

25. (Amended) The composition of [any one of claims 21 to 24] claim 21 in combination with written labeling instructions for administration of the particles by transdermal or transmucosal, high-velocity, powder injection.

26. (Amended) A unit dosage form of the composition of [any one of claims 21 to 24] claim 21.

27. (Amended) An article of manufacture for the transdermal or transmucosal delivery of a pharmacologically-active agent to a subject, which

article comprises a pharmaceutical composition of [any one of claims 21 to 24] claim 21 in a container containing a unit dose of active agent.

29. (Amended) The article of manufacture of claim 27 [or 28], wherein the active agent is a peptide or protein.

30. (Amended) The article of manufacture of [any one of claims 27 to 29] claim 27 in combination with written labeling instructions for administration o f the particles by transdermal or transmucosal, high-velocity, powder injection.

31. (Amended) A method for delivering a drug to a subject in need thereof, which method comprises preparing a pharmaceutical composition of [any one of claims 21 to 24] claim 24, accelerating said particles to a high velocity, and delivering said accelerated particles into a target skin or mucosal site.

33. (Amended) The [process] method of claim 31 [or 32], wherein the active agent is a peptide.